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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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☐ Additional inventors are being named on the ^ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

DEVICE, SYSTEM AND METHOD FOR IN VIVO SENSING

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 13 ☐ CD(s), Number
☒ Drawing(s) *Number of Sheets* 3
☐ Application Data Sheet. See 37 CFR 1.76 ☒ Other (specify) postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☐ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 05-0649
☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): 160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
☒ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

Date 30 / Dec / 2002

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REGISTRATION NO. *(if appropriate)* 37,912

Docket Number: P-5608-USP

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Provisional Application, Assistant Commissioner for Patents, Washington, D.C., 20231.

P-5608-USP

United States Provisional Patent Application For: DEVICE, SYSTEM AND METHOD FOR IN VIVO SENSING

FIELD OF THE INVENTION

The present invention relates to the field of in vivo diagnostics. More specifically, the present invention relates to a method for sensing, for example, imaging, a body lumen.

BACKGROUND OF THE INVENTION

Dyspeptic symptoms (dyspepsia) constitute a major reason for physician visits and referrals for gastroenterology consultation. Some pathologies of the gastrointestinal (GI) tract involve epithelial damage, erosions, and ulcers. For example, inflammation of the GI tract mucosa (typically in the stomach), such as gastritis, can be characterized, inter alia, based on the endoscopic appearance of the gastric mucosa (e.g., varioliform gastritis). Other pathologies may involve irregularities or abnormal appearances of folds, polyps or color indications (such as bleeding) on the GI tract wall. Detection of these pathologies at an initial stage plays an important role in enhancing the probability of a cure.

Screening populations for initial signs of GI tract pathologies is typically carried out by non invasive methods including x-ray series in which a patient intakes x-ray opaque (radio-opaque) material (barium, gastrographine, or others). The material resides for some time on the walls of the GI tract, enabling examination of the x-ray images of the GI tract. This technique has several drawbacks, namely, low detection rate and exposure to x-ray radiation. Other screening methods include viewing the GI tract walls or lumens by means of appropriate endoscopes. For example, flexible upper endoscopy is often performed to evaluate for a gastrointestinal etiology of pain such as mucosal inflammation (esophagitis, gastritis, duodenitis), ulceration, or a neoplasm. Risks associated with flexible upper endoscopy include injury to the bowel wall, bleeding, and aspiration. Upper endoscopy is usually performed under conscious sedation, which carries risks as well. Furthermore, patients typically need to take a day off of normal activities due to the lasting effects

of conscious sedation. Finally, the endoscopy procedure is clearly a cause of discomfort, pain and vomiting in many patients. Even the physical dimensions of the endoscope can be a cause for fear. Such risks, along with the prospect of incapacitation and fear, are often used as justifications by patients for delaying or altogether avoiding gastroscopic diagnosis.

Visualization of the GI tract, including the more difficult to reach areas, such as the small intestine, is possible today using an ingestible imaging capsule. Images of the GI tract are obtained by a miniature image sensor carried by the capsule and are transmitted to an external recorder to be later viewed on a workstation. Sensing other parameters of the GI tract, such as pH or temperature, are also possible by using ingestible transmitting capsules. Ingestible capsules may be moved through the GI tract by the natural movement of peristalsis. However, in larger lumens, such as the stomach or large intestine, the capsule may not cover the entire surface of the lumen wall. There is therefore a need for an effective method for sensing body lumens, a method which may, for example, be used for screening.

SUMMARY OF THE INVENTION

There is thus provided, according to embodiments of the invention, a method for sensing a body lumen. According to some embodiments an ingestible imaging capsule is inserted into a body lumen. A patient may be positioned in such a way so as to achieve corresponding positioning of the capsule within the patient's body lumen.

Controlled and repeatable positioning of a sensing device in vivo may be achieved according to the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

Figure 1 is a box diagram depicting a method for in vivo sensing according to an embodiment of the invention;

Figure 2 is a schematic presentation of a receiving unit placed on a patient's body during a procedure in accordance with an embodiment of the invention; and

Figure 3 is a schematic illustration of a device that is moved about a patient's stomach according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be appreciated by one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well known features may be omitted or simplified in order not to obscure the present invention.

According to an embodiment of the invention a sensing device is inserted in vivo and a patient is positioned in such a way so as to achieve corresponding positioning of the device within the patient's body lumen. Typically, a device used according to an embodiment of the present invention is an autonomous compact device, which can be easily moved through a body lumen. Body lumens may include cylindrical tube like lumens, such as blood vessels or the small intestine, through which a device may be moved by the natural motion of the lumen, e.g., peristalsis in the small intestine. Other body lumens may be voluminous and not necessarily content filled, e.g., the stomach or large intestine. Movement through voluminous lumens may not be effected by natural muscle movement.

According to one embodiment the device is an ingestible capsule. An ingestible capsule may include an in vivo sensor, such as a pH sensor, a temperature sensor, a pressure sensor an image sensor and so on. Typically, effective sensing of a lumen environment requires the sensor to be in the lumen for a minimal period of time and to survey most of the lumen volume.

According to an embodiment of the invention an imaging capsule shaped device may be used for sensing a patient's GI tract. The device may be, for example, similar to embodiments described in U.S. Patent No. 5,604,531 to Iddan et al., and/or WO 01/65995, entitled "A Device And System For In Vivo Imaging", published on 13 September, 2001, both of which are assigned to the common assignee of the present invention and which are hereby incorporated by reference. However, the device may be any sort of in-vivo sensor device and may have other configurations. A device typically includes an image sensor, such as a CCD or CMOS imager, an illumination source, such as an LED and an optical system for focusing images onto the image sensor. The device may further comprise a transmitter for transmitting image and other (e.g., non-image) information to a receiving device, and may include other components, such as, for example, a compression module for compressing data. The transmitter is typically an ultra low power radio frequency (RF) transmitter with high bandwidth input, possibly provided in chip scale packaging. The transmitter may also include circuitry and functionality for controlling the device. The transmitter may be, for example, an ASIC, "computer on a chip", microcontroller, etc., or other component. Components such as the image sensor, illumination source and transmitter may be mounted on a support, which may be, for example, a printed circuit board or plastic board or sheet. The support may be another structure, and components need not be mounted on a separate support.

The device may be ingested for obtaining in vivo images or other in vivo information. Typically, the device is swallowed by a patient and traverses the patient's GI tract, however, other body lumens or cavities may be imaged or examined, and the device need not be swallowable. For example, a device may be inserted into the female reproductive tract or urinary tract for obtaining in vivo data. Typically, the device transmits information (e.g., image information) in discrete portions. Each portion typically corresponds to an image or frame. Other transmission methods are possible. For example, the device may capture image or

other information once every half second, and, after capturing such an image, transmit the information to a receiving antenna. Other capture rates are possible. Typically, the image data recorded and transmitted is digital color image data, although in alternate embodiments other image formats (e.g., black and white image data) may be used. In one embodiment, each frame of image data includes 256 rows of 256 pixels each, each pixel including data for color and brightness, according to known methods. For example, in each pixel, color may be represented by a mosaic of four sub-pixels, each sub-pixel corresponding to primaries such as red, green, or blue (where one primary is represented twice). The brightness of the overall pixel may be recorded by, for example, a one byte (e.g., 0-255) brightness value. Other data formats may be used, and other image formats may be used.

Typically, located outside the patient's body in one or more locations, are a receiver, preferably including an antenna or antenna array, for receiving image and possibly other data from the in vivo device, a receiver storage unit, for storing image and other data, a data processor, a data processor storage unit, and an image monitor, for displaying, inter alia, the images transmitted by the device and recorded by the receiver. Typically, the receiver and receiver storage unit are small and portable, and may be worn on the patient's body during recording of the images. Typically, the data processor, data processor storage unit and monitor are part of a personal computer or workstation, which may include standard components such as a processor, a memory (e.g., storage, or other memory), a disk drive, and input-output devices, although alternate configurations are possible. In alternate embodiments, the data reception and storage components may be of another configuration. It should be emphasized that other embodiments may include a wired rather than wireless device. According to some embodiments online viewing of a body lumen may be performed, wherein in vivo data is transmitted directly, typically through antennas surrounding a patient's body, to a receiving unit in a workstation.

According to one embodiment, the imaging device is spherical or substantially spherical (which when used herein includes an ellipse shape). Such a shape may enable the device to glide over the typically moist (and thus substantially frictionless) surface of body lumens, such as the stomach, when it is moved over the surface. Also, for example, a spherically shaped device may glide over the ridges formed on GI tract lumen walls (such as the stomach wall) rather than get stuck in these ridges. In such a case, the motion of an imager within the device is relatively smooth and

continuous. This may be in contrast to devices of other shapes (e.g., oblong shapes), which may produce jumpy motion and non-continuous images in the same context.

An optional ballast or weight may be added to a portion of an imaging (or other sensing) device. Ballast may allow one portion, such as the image sensor, to be usually oriented in a fixed direction. In alternate embodiments the internal components of a device may be packaged so as to shift the center of gravity [CG] and create ballast in one portion of the device, for example, batteries and electronic components may be packaged at one end of a capsule so as to create ballast at that end. In such an embodiment, the images captured tend to be not of the wall on which the device is resting, in the case that the device is resting on a surface in a lumen, but rather include a view oriented outward from the wall. In a lumen which is relatively large (e.g., the stomach or large intestine), when the patient is oriented so gravity acts on the ballast or weight in a certain manner, the wall opposite the wall on which the device is resting is imaged, rather than a wall close to the device which may block the view of the imager. Such an embodiment may provide a relatively steady view of a lumen, and be easily oriented to portions of such lumens which are desired to be imaged. In alternate embodiments if sensing of a lumen wall is required, such as to sense a temperature or pH of a lumen wall tissue, ballast may be added to the sensing device so as to ensure positioning of the sensor in close vicinity of the lumen wall when the device is residing on the lumen wall. In yet further embodiments, a body lumen may be filled with a liquid to allow a sensing device to float or to be carried with the liquids to all parts of the lumen.

Reference is now made to Fig. 1, which schematically shows a method according to an embodiment of the invention. An in vivo sensing device, for example, a device as described above, is inserted in vivo (101), typically in to a patient's body lumen. The patient is positioned (102) typically to achieve a desired positioning of the in vivo sensing device in the patient's body and/or to control the timing of the in vivo sensing process. Other steps or series of steps may be used.

According to one embodiment the in vivo sensing device is inserted in vivo by swallowing. According to other embodiments a device may be inserted in vivo by using instruments such as endoscopes, needles, etc. Other inserting methods are possible according to additional embodiments of the invention. The patient may be positioned prior to the insertion of the sensing device or the positioning may commence after the device is inserted into the patient's body. According to one

embodiment positioning may include rotating or tilting a patient's body or parts of a patient's body. According to other embodiments positioning may include moving a patient's body or parts of a patient's body in a specific direction and/or at a specific rate and/or at predetermined intervals etc. It should be appreciated that the sequence of positioning of the patient's body directly affects the path taken by the device in vivo and accordingly affects the coverage of the body lumen. A patient's body may be prepped prior to insertion of the sensing device or at other points during the procedure. For example, a patient's lumen may be emptied (such as by performing an enema for the large intestine) or filled (such as by drinking a large volume of liquid), specific active ingredients may be ingested, for example, to achieve relaxation of muscles, (e.g., to alter peristalsis or to achieve vasodilation of blood vessels). The method according to an embodiment of the invention may include the step of receiving data transmitted from the in vivo sensing device (103). According to one embodiment in vivo data is transmitted from the device to a recorder worn by the patient and is later down loaded to a workstation for reviewing off line. According to yet another embodiment in vivo data may be transmitted directly to a workstation for online review. According to one embodiment the sequence of patient positioning may be dependant on online data review. For example, a patient may be positioned such that a first portion of his stomach may be viewed. If data obtained from the first portion shows the occurrence of a pathology in this portion the patient is not positioned according to the predetermined positioning sequence but rather he is delayed in the first position or alternatively, a different positioning sequence is applied in order to obtain more data from the first portion of the patient's stomach.

According to one embodiment there is provided a method for sensing a patient's esophagus. According to an embodiment of the invention an imaging capsule, such as an M2A™ imaging capsule, is inserted into a patient's esophagus and the patient is positioned such that, inter alia, the capsule stays in the esophagus for a minimal period that may be required to obtain significant data and to achieve a survey of most of the esophagus. A method for imaging the esophagus is exemplified by the following representative procedure. It will be appreciated that a person skilled in the art may adjust the procedure according to specific requirements or patient physic. The following Examples are exemplary only, and other steps or series of

steps, and other amounts or techniques, may be used according to embodiments of the present invention.

Examples

Example 1 - Procedure for Esophagus Capsule Endoscopy:

1. Placement of sensors (e.g. antennas) on a patient's back (see Fig. 2 – measurements are shown from center to center of sensors. Measurements can be varied according to patient's physic), after which the patient may lie on his back. Other numbers of sensors or positions may be used.

2. Attach sensor array to recorder.

3. Rinsing saliva- in order to minimize the amount of saliva in the esophagus:

    i. Patient is positioned lying down or so that he may immediately lie down.

    ii. About 250cc of water are sipped by the patient in a series of small sips. The last sip may be used to swallow an M2A™ imaging capsule (glycerin or oil (e.g., 3-5 ml) may be also used to minimize amount of saliva). Other amounts may be used.

    iii. During this process the patient typically is requested not to speak.

4. Ingestion of imaging capsule:

    i. When swallowing the capsule patient typically should take care to have the imaging side of the capsule pointing down into the pharynx.

ii. Patient should assume a horizontal position and swallow capsule (optionally – swallowing with head slightly raised and laying down immediately after swallowing).

iii. Patient should keep his mouth open for 3 minutes after swallowing.

5. Start positive inclination by raising torso in a stepwise manner of 20 –30 degrees every minute.

6. When reaching sitting position wait 1 minute before allowing patient to stand up.

According to one embodiment the sensors are connected directly to the workstation and the procedure is carried out with online viewing of the patient's esophagus.

According to another embodiment there is provided a method for sensing a patient's stomach. According to an embodiment of the invention an imaging capsule, such as an M2A™ imaging capsule, is inserted into a patient's stomach and the patient is positioned such that, inter alia, the capsule senses of the stomach body, including remote areas such as the cardia, fundum, antrum and the pyloric canal. A method for imaging the stomach is exemplified by the following representative experiment and procedure. It will be appreciated that a person skilled in the art may adjust the procedure according to specific requirements or patient physic.

Example 2 - Procedure for Stomach Capsule Endoscopy:

1. While lying flat on his left side, the patient swallows an M2A™ imaging capsule with 50 ml of water;
2. The patient is positioned Back Trendelenburg –10 to –20 degrees for about 1 minute;
3. The patient is positioned on his left side with his head elevated at 45 degrees for about 1 minute;
4. The patient is positioned on his left side with his head elevated at 60 degrees for about 1 minute;

5. The patient is positioned on his left side with his head elevated at 80 degrees for about 1 minute;
6. The patient is positioned flat on his back for about 1 minute;
7. The patient is positioned flat on his left side for about 1 minute;
8. The patient is positioned flat on his back again for about 1 minute;
9. The patient is positioned flat on his abdomen for about 1 minute;
10. The patient is positioned flat on his right side for about 1 minute.

An experiment was carried out to test the above positioning procedure. The capsule images are viewed on-line throughout the procedure, which lasts approximately 30 minutes. The subject is directed through the positioning set, and a fluoroscopic image of the stomach is captured in each position. At completion of the positioning set the subject is released. It was anticipated that each change in position of the patient would move the capsule along a predictable path to a particular region of the stomach.

Results:

Nine trials were conducted using the above procedure, with some variation, especially in the early trials. In all the trials, the capsule reached every region of the stomach at least once, except the pylorus. In two trials, the capsule also reached the pylorus, in one case after 23 minutes and in the other case after 31 minutes. Trial duration varied from 22 to 37 minutes. Image quality was good in most cases. The patient ingests 50 ml of contrast medium in water. The results are summarized in table no. 1.

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Table No. 1

Required EndPoint	Position Set	Anticipated Path of Capsule	Validated by Spot Fluoroscopy								
Subject ID			200	201	202	203	204	206	207	208	209
→ FUNDUS	Back Flat	Fundus	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Left Flat	Fundus or Body	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Back Minus 10 deg	Fundus	Y	Y	Y	Y	Y	Y	Y	Y	Y
→ ANTRUM	Left 45 degrees	Fundus or Body	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Left 60 degrees	Body		Y	Y	Y	N	Y	Y	Y	N
	Left 80 degrees	Antrum	Y	Y	Y	Y	Y	Y CELAI	Y	Y	Y
→ FUNDUS	Back Flat	Fundus or Antrum	Y	Y	Y	Y	Y	Y	N	Y	Y
	Left Flat	Body			Y	Y	Y	N	Y	Y	Y
	Back Flat	Fundus	Y	N	Y	Y	Y	Y	Y	Y	Y
→ PYLORUS	Abdomen Flat	Pylorus or Antrum	Y	N	Y	Y	N	Y	N	N	Y
	Right Flat	Pylorus	N	N	N	N	N	N	N	N	N
		Pylorus as per video	N	N	Y	N	N	N	N	Y	N
		Pylorus Arrival Time			031:13					023:33	
		Recording Time	024:34	026:43	037:09	026:59	022:33	022:53	024:05	023:59	024:24
All Regions Covered at Some Point During Capsule Path			Except Pylorus	Except Pylorus	YES	Except Pylorus	Except Pylorus	Except Pylorus	Except Pylorus	YES	Except Pylorus

Conclusions

1. The positioning set is successful in moving the capsule in a predictable manner to all areas of the stomach, except the pyloric region.
2. In only 2 cases out of 9, the capsule reached the pylorus within the 30-minute trial time.
3. The capsule did not pass into the duodenum within the 30-minute trial time in any of the trials.
4. Sensor placement: It was concluded in an investigation of the results that no gaps occurred due to low level sensor signals. It is possible that a single sensor would be sufficient for gastric screening.

Fig. 3 schematically illustrates a swallowable capsule that is moved about a patient's stomach according to the above Procedure for Stomach Capsule Endoscopy. It can be seen that the capsule follows a track that covers most of the stomach body, including remote areas such as the cardia, fundum, antrum and the pyloric canal.

Thus, a method according to embodiments of the invention provides a means for predictably and controllably moving a device in a body lumen. According to various embodiments of the invention a required area in a body lumen may be covered at a desired time schedule, thereby providing an effective and controllable tool for diagnosing and/or screening body lumens.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims, which follow.

We claim:

1. A method for in vivo sensing substantially as described hereinabove and in the drawings.
2. A system for in vivo sensing substantially as described hereinabove and in the drawings.

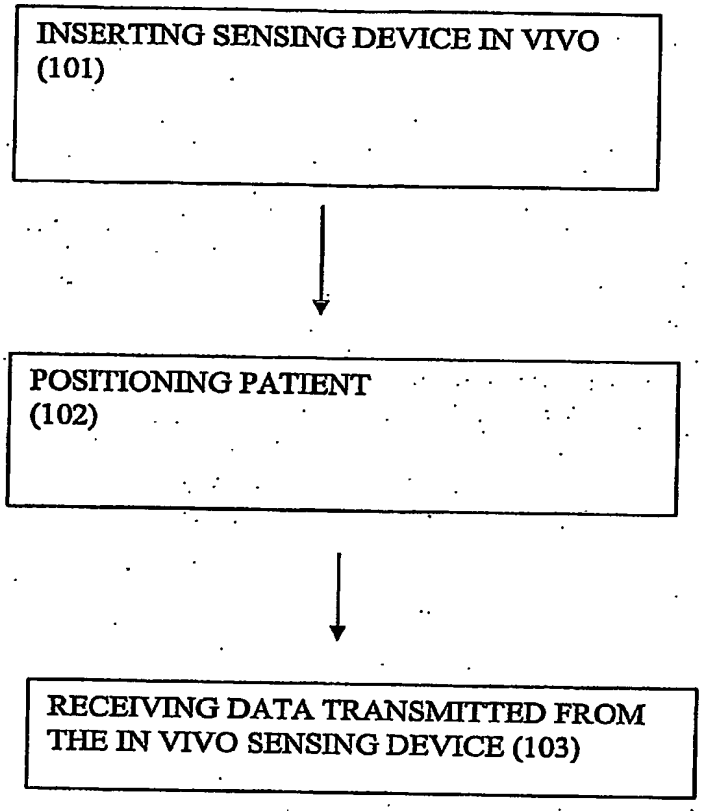
INSERTING SENSING DEVICE IN VIVO (101)
POSITIONING PATIENT (102)
RECEIVING DATA TRANSMITTED FROM THE IN VIVO SENSING DEVICE (103)

FIGURE 1

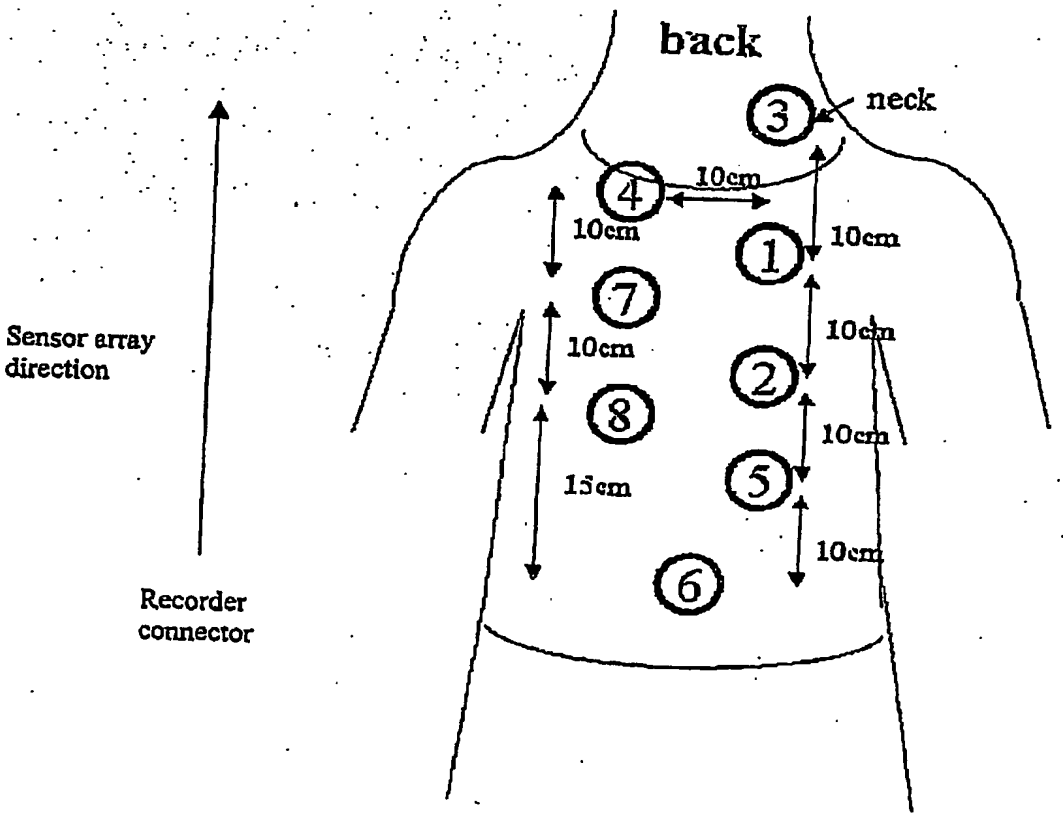
back
neck
3
4
10cm
10cm
1
10cm
7
10cm
10cm
2
8
10cm
15cm
5
10cm
6
Sensor array direction
Recorder connector

FIGURE 2

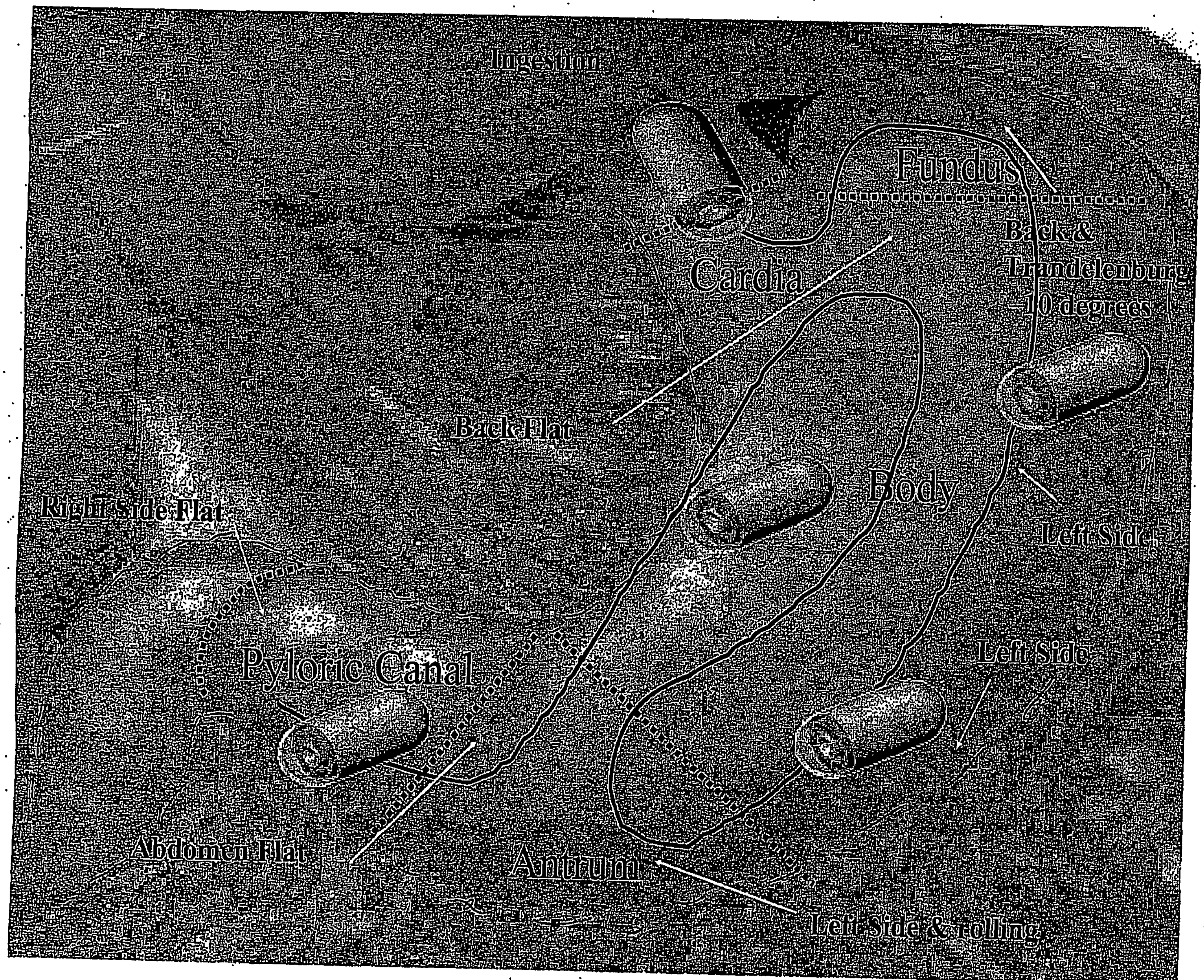

Fig. 3